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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|----------------|----------------------|------------------------|-----------------|
| 09/480,260 | 01/11/2000 | Pavel Hamet | 1171-99 | 4119 |
| 7 | 590 12/02/2004 | | EXAM | INER |
| Gerald F. Swiss | | | MELLER, MICHAEL V | |
| Foley & Lardner LLP. Three Palo Alto Square | | | ART UNIT | PAPER NUMBER |
| 3000 El Camino Real Suite 100 | | | 1654 | |
| Palo Alto, CA 94306-2121 | | | DATE MAILED: 12/02/200 | 4 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | A | | | | |
|---|---|--|--|--|--|--|
| | Application No. | Applicant(s) | | | | |
| Office Asking Comments | 09/480,260 | HAMET ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Michael V. Meller | 1654 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a rep If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a reply be timely within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE. | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on <u>04 May 2004</u> . | | | | | | |
| 2a)⊠ This action is FINAL . 2b)☐ This | · | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>19-28</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>19-28</u> is/are rejected. | ☑ Claim(s) <u>19-28</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/o | or election requirement. | • | | | | |
| Application Papers | | t | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the price | ority documents have been receive | | | | | |
| application from the International Burea * See the attached detailed Office action for a lis | | ed. | | | | |
| Goo and databased comes design for a new or and a super- | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Paper No(s)/Mail Date. | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-946) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) 6) Other: | | | | | | |

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 19-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention is not enabled for the **claimed** method. Applicant argues that one of ordinary skill in the art would know how to administer the claimed invention, but that is not the issue at hand. Alzheimer's disease, senile dementia and Parkinson's disease are all diseases for which there is no known cure or prevention. The invention reads on preventing these diseases see applicant's specification at page 5-6 where it is established that Parkinson's and Alzheimer's are associated with excessive degrees of apoptosis. Further, there is no evidence on the record that Alzheimer's or Parkinson's was prevented. Thus, the level of enablement to prevent against such diseases is quite high. Applicant's claims are drawn to a method which is very unbelievable on its face.

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This is due to the fact that there is no prevention for these conditions/diseases. Thus, without conclusive evidence to show that these diseases have been prevented, the invention is not enabled by the instant specification.

Applicant argues that they are not preventing Alzheimer's or Parkinson's which have no known prevention or cure but in fact they are allegedly "alleviating or protecting against the *symptoms* of a neurological medical disorder *involving* accelerated rates of apoptosis in a mammalian body". Who would not think that, that refers to Alzheimer's or Parkinson's when such diserases or well known to be neurological medical disorders. Further, the claims are limited to *involving* accelerated rates of apoptosis in a mammalian body not mediating it. This still reads on preventing diseases such as Parkinson's since these diseases are involving accelerated rates of apoptosis. Applicant even admits on pages 5- 6 of their specification, that increased rates in apoptosis are known to occur in disease/conditions such as Alzheimer's and Parkinson's.

Once again it is emphasized that the claims are drawn to "alleviating or protecting against the *symptoms* of a neurological medical disorder *involving* accelerated rates of apoptosis in a mammalian body" not alleviating or protecting against the *symptoms* of a neurological medical disorder <u>mediated by</u> accelerated rates of apoptosis in a mammalian body.

It is suggested that applicant limit the claims to treatment. If applicant limits the claims to treatment the invention may be allowable.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael V. Meller Primary Examiner Art Unit 1654

MVM